



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

2279 '02 JUN 28 A9:15

JUN 21 2002

Mr. Ira L. Goldberg  
President  
Source Naturals, Inc.  
23 Janis Way  
Scotts Valley, California 95066

Dear Mr. Goldberg:

This is in response to your letters of February 2, 2002 and May 13, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Policosanol Cholesterol Complex** uses the claim "...help maintain cholesterol levels within the normal range." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

The product **Gluco-Science™** uses the claim "Products that support healthy blood sugar levels...." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claim about control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar level that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

975-0163

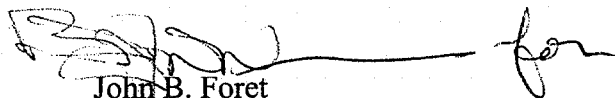
LET 619

Page 2 - Mr. Ira L. Goldberg

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret", followed by a horizontal line and a small flourish.

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

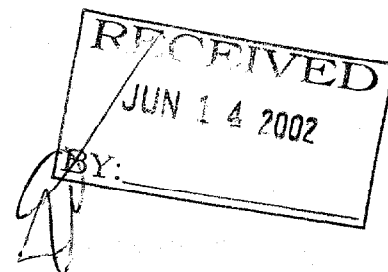
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

Source Naturals, Inc.  
Scotts Valley, CA 95066

February 02, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW.,  
Washington, D.C. 20204



RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Gluco-Science™ a dietary supplement. Source Naturals® is the manufacturer of Gluco-Science™.

Statements being made in the labeling of Gluco-Science™:

- (1) Products that support healthy blood sugar levels are projected to be among the industry's top five growth areas.
- (2) This Bio-Aligned Formula™ supports multiple body systems:  
Glucose/carbohydrate metabolism, insulin/pancreatic activity, heart and circulatory system, nervous system, and vision.

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.

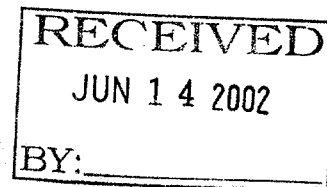
Ira L. Goldberg  
President, Source Naturals, Inc.

80857

Source Naturals®  
23 Janis Way  
Scotts Valley, CA 95066

May 13, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW., Washington, D.C. 20204



RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of, Policosanol Cholesterol Complex a dietary supplement. Source Naturals® is the manufacturer of Policosanol Cholesterol Complex.

Statements being made in the labeling of Policosanol Cholesterol Complex:

- (1) Bio-Aligned Formula supports multiple body systems: heart, blood vessels, nervous system, thyroid, liver and gastrointestinal tract.
- (2) Provides 500 mg of curcumin, the amount shown in research to reduce serum lipid peroxides and help maintain cholesterol levels within the normal range.
- (3) The antioxidant green tea inhibits LDL oxidation and promotes healthy blood vessels, according to animal and *in vitro* studies.
- (4) Myricetin, a powerful antioxidant, inhibits LDL oxidation, according to *in vitro* research.

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.

  
Ira L. Goldberg  
President, Source Naturals®

80857